REMARKS

Summary of Office Action

In the Office Action of May 15, 2008 the Examiner withdrew the finality of the previous Office Action based on the Panel Decision from Pre-Appeal Review reported on March 6, 2008. Also as a result of that Panel Decision, the rejection of claim 1-7 and 10-18 under 35 U.S.C. 103(a) over U.S. Patent No. 4,574,084 to Berger (hereinafter "Berger") in view of U.S. Patent No. 5,782,992 to Frangione was withdrawn. However, the Examiner made a new rejection of claims 1-7 and 10-18 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. No further issues were raised.

Summary of Amendment

Claims 1-7 and 10-18 remain pending in the application. Reconsideration of the rejection of the claims is respectfully requested in light of the arguments provided below.

Applicant's Response

Rejection of Claims 1-7 and 10-18 under 35 U.S.C. 112, First Paragraph

The Examiner rejected claims 1-7 and 10-18 as allegedly failing to comply with the enablement requirement under 35 U.S.C. 112, first paragraph. In particular, the Examiner asserts that Applicant has failed to provide an enabling disclosure for using chlorite in combination with a peroxy compound without degrading the chlorite into chlorine dioxide during storage at about room temperature (*see, e.g.,* first full paragraph of page 2 of Office Action). The Examiner further cites Berger as "teaching against" the preparation of a composition that remains intact without degrading into chlorine dioxide (*see, e.g.,* final full paragraph of page 2 of Office Action). The Examiner concludes that one of ordinary skill in

the art "would be burdened with undue experimentation to determine all peroxy compounds in combination with all chlorite compounds which can form a stable composition without degradation of chlorite to chlorine dioxide" (final full paragraph of page 3 of Office Action). This rejection is respectfully traversed.

Claim 1 is drawn to an antimicrobial composition comprising *from about 0.001 wt. % to about 0.2 wt. % chlorite compound* and *from about 0.001 wt. % to about 0.05 wt. % peroxy compound*, the composition being at *a pH range between about 6.0 and 8.8*. The claim further requires that the composition "remains intact without degrading the chlorite compound into chlorine dioxide during storage at room temperature." This claim is fully enabled by the guidance and examples set forth in the disclosure, as well as by what is known and understood in the prior art, including the prior art as taught by Berger. Accordingly the composition of claim 1 and the claims depending therefrom are fully in compliance with the enablement requirement under 35 U.S.C. 112, first paragraph.

The Examiner presents an analysis of the eight factors from *in re Wands*, 8 USPQ2d 1400 (Fed Cir. 1988) to evaluate the enablement of the instant claims. Applicant will thus address each of these factors and the Examiner's conclusions therefrom in rebutting the reasons for rejection of the claims.

1. Nature of the Invention:

Applicant agrees with the Examiner that the claims are drawn to an antimicrobial composition comprising a chlorite compound in combination with a peroxy compound.

2. State of the Prior Art:

The Examiner argues that the prior art, as embodied by the Berger patent, "teaches against the preparation of a composition that remains intact without degrading the chlorite compound into chlorine dioxide" (final full paragraph on page 2 of Office Action). Applicant presumes that what the Examiner means in saying that Berger "teaches against" the instant composition, is that Berger teaches that the compositions of chlorite taught therein

do in fact degrade into chlorine dioxide, which would appear to contradict the recitation of the instant claims as well as the teachings of the instant application. Nonetheless, by viewing the teachings of Berger in their entirety, as well as the guidance provided in the instant application, it is clear that the composition as instantly claimed is not contradictory to the teachings of Berger, even though Berger does indeed very much *teach against* the *desirability* of forming a composition that does not degrade into chlorine dioxide.

In particular, it is noted that Berger teaches that a "stable" solution is provided at a pH value of 7 (*see, e.g.,* Abstract), which value is within Applicant's range of from about pH 6.0 and about pH. 8.8. Berger also teaches that peroxy compounds act to *stabilize* the chlorite compounds in the composition (*see, e.g.,* column 2, lines 30-35). Accordingly, one of ordinary skill in the art upon reading the Berger reference would understand that the stability of the chlorite-containing composition is dependent upon the pH of the composition, **as well as on the amount of peroxy compound that is provided.**

Where Berger deviates from the instant invention to obtain a "stable" composition, which nonetheless contains chlorine dioxide, is in the *relative amount* of chlorine dioxide provided. In particular, Berger teaches that concentrations of peroxy compound should be 0.001 to 0.01 M in the finished solutions (*see e.g.,* column 2, lines 57-68). Berger further teaches that higher concentration of peroxy compounds have no advantage and "frequently exclude the sought effects" (column 3, lines 3-6). Berger teaches a finished solution that contains 100 grams (1.48 mol) of chlorine dioxide (in chlorite form) per liter along with 0.0022 mol peroxy compound (s*ee, e.g.,* column 5, lines 3-6). In other words, **Berger exemplifies a composition having a chlorite to stabilizing peroxy molar ratio of 674:1**. In the only other preparation example given, Berger teaches 0.5 grams of 30 % by weight hydrogen peroxide (0.0044 mol hydrogen peroxide) solution combined with approximately 270 grams of sodium chlorite (2.99 mol sodium chlorite) **for a composition having a chlorite to stabilizing peroxy molar ratio of 680:1** (*see, e.g.,* column 9, lines 40-45).

Furthermore, while Berger does not specifically teach an example of a composition having a ratio of chlorite to stabilizing peroxy of less than 674:1, even if one were to extrapolate from the peroxy molar concentration taught in these examples (0.0022 molar) to the maximum molar concentration (0.01 molar) taught by Berger as being suitable for the compositions, the molar ratio of chlorite to stabilizing peroxy compounds would still be at least 148:1. In fact, it is quite clear that Berger would not want a lower ratio because Berger teaches that the higher concentrations of peroxy are detrimental to the sought after effects (namely chlorine dioxide generation).

In contrast, in claim 1 of the instant application, Applicant claims an antimicrobial composition having about 0.001 wt.% to about 0.20 wt.% chlorite compound and from about 0.001 wt.% to about 0.05 wt.% peroxy compound, which amounts are also taught in the instant specification (*see, e.g.,* Abstract). Assuming that the chlorite compound is sodium chlorite and the peroxy compound is hydrogen peroxide, in analogy with the teachings of Berger, **the maximum molar ratio of chlorite to stabilizing peroxy compound possible with Applicants composition would be 75:1**, given the minimum amount of stabilizing peroxy (0.001 wt.%) and the maximum amount of chlorite (0.20 wt.%). Thus, Applicant's composition is "stable" and does not generate chlorine dioxide, both because the composition is maintained within the pH range of from about 6.0 to 8.8, **as well as because Applicant's composition provides a greater proportion of stabilizing peroxy compound per chlorite compound** than the compositions taught in the Berger reference. The instantly claimed compositions thus provide greater stability for the chlorite compound in the composition, as compared to the compositions of Berger, such that the chlorite compound does not degrade into chlorine dioxide.

Accordingly, it is clear that one of ordinary skill in the art would not find the instantly claimed composition inconsistent with the teachings of Berger, because while both the instant composition and Berger teach the importance of maintaining the proper pH to provide a "stable" composition, one of ordinary skill would further recognize that Berger teaches the desirability of limiting the amount of peroxy compound provided, in order to allow for the

generation of chlorine dioxide, whereas the composition of the instant invention seeks to keep the chlorite intact and thus increases the amount of peroxy compound provided therein.

It is furthermore emphasized that while the instantly claimed composition is not inconsistent with that of Berger, the claimed composition is nonetheless non-obvious over the teachings of Berger, because Berger is specifically directed to the formation of a stable chlorite composition having a controlled generation of chlorine dioxide therein, to provide biocidal effects thereby, whereas the instantly claimed composition is capable of remaining intact without degrading the chlorite compound into chlorine dioxide during storage at about room temperature. For example, as described in the Pre-Appeal Brief Request for Review submitted on November 23, 2007, the Berger patent is replete with statements indicating that ***the formation of chlorine dioxide provides the beneficial disinfecting property***. *See, e.g.,* Column 3, lines 41-43 ("...chlorine dioxide removal...leads to an undesired weakening of the system in the sense of the invention"); Column 5, lines 5-6 ("This finished solution contains approximately 100g of chlorine dioxide per liter."); Column 6, lines 21-30 ("...chlorine dioxide, which is highly effective for disinfection purposes, is formed...The finished solution generally contains 8 to 15% by weight of chlorine dioxide, the range 10 to 12% by weight being regularly particularly advantageous."); Column 9, lines 11-28 ("...the stabilized, modified, aqueous chlorite solution according to the invention can be advantageously used wherever it is to lead to an oxidative action, particularly due to the formation of chlorine dioxides...A particular advantage of the chlorite solution according to the invention is that it generally permits a **100% conversion of the chlorite into chlorine dioxide** in a wide pH-range..."). Accordingly, as the intent of Berger is to provide a composition that generates chlorine dioxide to provide biocidal and disinfecting properties, one of ordinary skill in the art would not have found it obvious based on the teachings of Berger to devise the composition as claimed that does not degrade into chlorine dioxide.

Accordingly, the composition as claimed is fully consistent with, and enabled by, the state of the prior art as exemplified by the Berger patent.

3. The Relative Skill of Those in the Art:

Applicant agrees with the Examiner that the relative skill of those in the art is high, which furthermore weighs heavily in Applicant's favor as those of ordinary skill in the art would be able to make and use the invention based on the guidance provided in the specification and in the prior art, such as Berger, without requiring undue experimentation.

4. The Predictability or Unpredictability of the Art:

Applicants agree with the Examiner that the chemical arts are, in general, considered to be unpredictable, especially with regards to the ability to predict the chemical activity of very new and heretofore unknown compounds. Nonetheless, the practice of the chemical arts quite often depends upon the identification of certain trends in chemical properties for known compound that can be used to evaluate the likelihood of certain activities under particular conditions. For example, if a known compound is understood to be an acid, then those of ordinary skill in the art would understand that increasing the amount of the compound in a composition would increase the acidity (and decrease the pH) thereof, whereas decreasing the amount would decrease the acidity (and increase the pH). As another example, if a known compound is understood to be a "stabilizing agent," then it would be understood by those of ordinary skill in the art that increasing the amount of the stabilizing agent would likely result in increased stability of the medium under study, whereas decreasing the amount of stabilizing agent would likely promote the destabilization of the medium. Thus, the general trend of stability in relation to increasing/decreasing amounts of stabilizing agent can be understood to be relatively predictable, particularly in the case where reference examples (such as the examples of Berger), are already in existence. Accordingly, while the chemical arts in general may be understood to be relatively unpredictable, the general trends for properties of known chemical compounds are often well understood by those of ordinary skill in the art, and thus the use of compounds in accordance with these trends can in fact be relatively predictable.

5. The Breadth of the Claims:

Applicant respectfully disagrees with the Examiner's assertion that the claims are very broad. While claim 1 is drawn to an anti-microbial composition comprising a chlorite compound and a peroxy compound, the claim further specifies that the chlorite compound be provided in an amount of from about 0.001 wt. % to about 0.2 wt. %, and that the peroxy compound be provided in an amount of from about 0.001 wt.% to about 0.05 wt.%. Claim 1 also requires that a pH range of the composition be kept between about 6.0 and about 8.8. Thus, the claim sets forth particular ranges for the chlorite and peroxy compounds, as well as the pH of the composition, that define the composition within suitable parameters, and thus the claim is not considered to be overly broad.

Furthermore, the class of compounds corresponding to "chlorite" compounds and "peroxy" compounds are well known to those of ordinary skill in the art, as is also taught by Berger (*see, e.g.,* column 1, lines 15-30 and column 2, lines 24-53), and thus the recitation of these compounds is not overly broad to those of ordinary skill.

6. The Amount of Direction or Guidance Provided:

Applicant takes significant exception to the Examiner's assertion that the specification "fails to provide guidance in preparing an antimicrobial composition by combining a chlorite compound with a peroxy compound without degrading into chlorine dioxide" (Section six on page 3 of Office Action). On the contrary, the instant specification provides guidance with regards to the suitable percent by weight of each compound that should be provided, i.e., about 0.001 wt. % to about 0.20 wt.% chlorite and from about 0.001wt. % to about 0.05 wt. % peroxy compound (*see, e.g.,* Abstract), and provides further guidance with regards to the pH range necessary to achieve a stable composition, namely a pH in the range of from about 6.0 and about 8.8 (*see, e.g.,* Abstract). The specification further describes that maintaining the proper, relatively neutral pH range is crucial, because the addition of acid undesirably generates chlorine dioxide (*see, e.g.,* paragraph [0010] of specification).

Thus, one of ordinary skill in the art would understand upon reading the specification that the compositions according to the invention could be prepared by selecting amounts of chlorite and peroxy compounds within the claimed ranges, and maintaining the composition at the relatively neutral pH of from about 6.0 to about 8.8. It is furthermore noted that the specification points to particular preferred chlorite and peroxy compounds, namely sodium chlorite and hydrogen peroxide, and also refers to a preferred pH range of 7.0-7.4 (*see, e.g.,* paragraph [0058]), providing further guidance in the selection of parameters for the composition to those of ordinary skill in the art. The specification also teaches that a composition containing 400 ppm chlorite plus 100 ppm hydrogen peroxide remained stable beyond 18 months at room temperature (*see, e.g.,* paragraph [0058]).

It is furthermore noted that the Specification provides numerous examples of such compositions that could be used by those of ordinary skill in the art as guidance for formulation of the inventive compositions. For example, Formulas 1-2 are set forth as examples of "Stable Chlorite/Peroxide Liquid Solutions," whereas Formula 3 is set forth as an example of a "Stable Chlorite/Peroxide Gel," and Formula 4 is set forth as an example of a "Stable Chlorite/Peroxide Ophthalmic Solution." The specification even further provides examples of particular compositions with the weight percent of each ingredient specified along with the pH, including a composition used to treat psoriasis (*see, e.g.,* paragraphs [0158]-[0171]), a composition used for treatment of dry eye conditions (*see, e.g.,* paragraphs [0180]-[0184], and compositions for the cleaning of contact lenses (*see, e.g.,* paragraphs [0188]-[0195]), as well as *in-vitro* and *in-vivo* evaluations of the antimicrobial efficacy of the compositions (*see, e.g.,* paragraphs [0196]-[0207]). These examples thus serve to provide further guidance to those of ordinary skill in the art with regards to the preparation of the antimicrobial compositions according to the invention.

Accordingly, it is considered that one of ordinary skill in the art would have more than adequate guidance in the preparation of antimicrobial compositions according to the instant invention, based on the teachings of the specification as well as the examples of Formulas set forth therein.

7. The Presence and Absence of Working Examples:

Applicant objects to the Examiner's assertion that the examples in Applicant's specification merely show the combination of sodium chlorite and hydrogen peroxide "without demonstrating the lack of degradation of chlorite to chlorine dioxide" (Section 7 on page 3 of Office Action).

Applicant respectfully directs the Examiner to Figures 1-7 and Experiments 1-7 (paragraphs [0094-[0155]) of the instant Specification, which clearly demonstrate that the composition is capable of remaining intact without degradation of the chlorite compound to chlorine dioxide. These Experiments evaluated the inventive compositions at pH levels within the claimed range, and in particular at pH levels of 7.3, 8.0, 8.8, 7.0, 6.44 and 6.0 (*see, e.g.,* Experiments 1-6), and compared to a composition having the same formula at a pH of 1.5 (*see, e.g.,* Experiment 7). The compositions containing chlorite and peroxy were prepared, and the compositions were then placed in a UV-Vis. spectrophotometer to evaluate whether degradation of the chlorite to chloride dioxide had occurred. The inventive compositions all exhibited a peak corresponding to the presence of sodium chlorite at 260 nm, and were absent any peaks corresponding to chlorine dioxide at 355-358 nm (*see, e.g.,* Figures 1-6 and paragraphs [0101], [0109], [0116], [0122], [0129] and [0135]), thus demonstrating that each composition "has only sodium chlorite, and does not contain any quantities of chlorine dioxide … [indicating that] the sodium chlorite is not breaking up and forming the chlorine dioxide" (paragraph [0102]). In contrast, the comparative composition having the pH of 1.5 did *not* show any peaks corresponding to the presence of sodium chlorite at 260 nm, and instead had a large peak corresponding to chlorine dioxide at 355-358 nm (*see, e.g.,* paragraph [0141]), demonstrating that the composition was very unstable, and that *all* of the chlorite present in the liquid solution was converted into the undesirable chlorine dioxide degradation product.

Furthermore, as was discussed in greater detail in the previous section, the specification provides numerous examples of stable antimicrobial compositions according to

the invention that do not form the chlorine dioxide degradation product, such as Formulas 1-4 disclosed in the specification.

Accordingly, contrary to the Examiner's assertion, the Specification provides numerous working examples and even evidence of the stability and lack of degradation of the chlorite compound to chlorine dioxide, and thus provides substantial guidance to those of ordinary skill in the art in the preparation of the claimed antimicrobial compositions.

8. The Quantity of Experimentation Necessary:

The Examiner argues that one of ordinary skill in the art would be "burdened with undue experimentation to determine all peroxy compounds in combination with all chlorite compounds which can form a stable composition without degradation of chlorite to chlorine [dioxide]" (Section 8 on page 3 of Office Action. Applicant respectfully disagrees with this conclusion.

In particular, Applicant submits that the guidance provided in the instant Specification, coupled with what was known to those of ordinary skill in the art, for example as taught by Berger, is more than sufficient to allow those of ordinary skill in the art to prepare the compositions according to the instant invention without requiring undue experimentation. To summarize some of the arguments provided above in support of the enablement of the claims, it is noted that the class of compounds that are "chlorite" and "peroxy" compounds are well known and immediately envisionable to those or ordinary skill in the art, as described for example in paragraph [0058] of the instant invention as well as in Berger (*see, e.g.,* column 1, lines 15-30 and column 2, lines 24-53), and thus one of ordinary skill would not be required to engage in undue experimentation to determine all compounds corresponding to those claimed. The amounts of each of the chlorite and peroxy compounds to provide in the composition are also limited to only those in the particular claimed ranges, and the pH is required to be maintained within the particular range of from about 6.0 to about 8.8, and thus any experimentation required would only be limited to those weight percentages and pH levels within the claimed ranges.

The Specification also provides numerous examples of suitable Formulas corresponding to the composition as claimed, and even demonstrates proof of the lack of degradation of the chlorite to the chlorine dioxide (*see, e.g.,* Figures 1-7), and thus provides several bases or starting points for the development of the formulas. Finally, the specification's teachings regarding the stability of the composition and lack of degradation of the chlorite compound to chlorine dioxide is not inconsistent with what was known in the prior art, as exemplified for example by Berger, because peroxy compounds were known to "stabilize" the chlorite compounds, and thus one of ordinary skill in the art would understand that providing a greater proportion of the peroxy compound would likely impart greater stability to the composition and less chlorine dioxide generation.

Accordingly, it is considered that one of ordinary skill would be required to engage in only *routine experimentation* to make and use the invention as claimed. It is furthermore noted that while it is possible that the concentration and/or ratios of the ingredients could require fine-tuning, such experimentation would be considered to be only routine to those of ordinary skill in the art, particularly in view of the substantial guidance provided in the specification. Those of ordinary skill in the chemical arts would not find it to be undue experimentation to test, evaluate and adjust compositions in accordance with the general trends known for the properties of the compounds therein, as discussed above. Applicant furthermore notes that, with regards to the amount of experimentation that is considered reasonable, it has been held that "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, as the specification and the state of the art provide abundant guidance as to the direction in which experimentation, if needed, should proceed, it is deemed that those of ordinary skill in the art would not be required to engage in undue experimentation to make and use the invention as claimed.

Claim 1 and the claims depending therefrom are therefore fully enabled by the Specification as required by 35 U.S.C. 112, first paragraph, and the rejection of these claims is respectfully requested to be withdrawn.

Conclusion

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. 112. Applicant therefore respectfully requests that the Examiner indicate allowance of each and every pending claim of the present invention. Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and believed to be appropriate.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 8/11/08 By: _____

Kit M. Stetina
Registration No. 29,445
STETINA BRUNDA GARRED & BRUCKER
75 Enterprise, Suite 250
Aliso Viejo, California 92656
Telephone: (949) 855-1246
Fax: (949) 855-6371

Customer No.: 007663

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